General

Guideline Title

Congress of Neurological Surgeons systematic review and evidence-based guideline for the diagnosis of patients with positional plagiocephaly: the role of imaging.

Bibliographic Source(s)

Mazzola C, Baird LC, Bauer DF, Beier A, Durham S, Klimo P Jr, Lin AY, McClung-Smith C, Mitchell L, Nikas D, Tamber MS, Tyagi R, Flannery AM. Congress of Neurological Surgeons systematic review and evidence-based guideline for the diagnosis of patients with positional plagiocephaly: the role of imaging. Neurosurgery. 2016 Nov;79(5):E625-6. [2 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the levels of recommendations (I-III) are provided at the end of the "Major Recommendations" field.

Recommendations

1. Clinical examination is recommended for the diagnosis of plagiocephaly, and imaging is rarely necessary, except in cases in which clinical diagnosis is equivocal.
   Strength of recommendation: Level III—low clinical certainty
2. In cases in which the clinical examination is equivocal, skull x-rays or ultrasound imaging of the suspect suture is recommended.
   Strength of recommendation: Level II—moderate clinical certainty
3. In cases in which the clinical examination is equivocal, surface imaging (computer-based topographical scans) or stereophotogrammetry is recommended for the assessment of infants with plagiocephaly without synostosis.
   Strength of recommendation: Level III—low clinical certainty
4. Only for infants in whom x-rays or ultrasound is nondiagnostic, a computed tomography scan is recommended for definitive diagnosis.
   Strength of recommendation: Level III—low clinical certainty

Definitions

Classification of Evidence and Levels of Recommendation on Diagnosis

Class I Evidence Level I (or A) Recommendation	Evidence provided by one or more well-designed clinical studies of a *diverse* population using a "gold standard" reference test in a blinded evaluation appropriate for the diagnostic applications and enabling the assessment of sensitivity, specificity, positive and negative predictive values, and, when applicable, likelihood ratios.
Class II Evidence Level II (or B) Recommendation	Evidence provided by one or more well-designed clinical studies of a *restricted* population using a "gold standard" reference test in a blinded evaluation appropriate for the diagnostic applications and enabling the assessment of sensitivity, specificity, positive and negative predictive values, and, when applicable, likelihood ratios.
Class III Evidence Level III (or C) Recommendation	Evidence provided by expert opinion or studies that do not meet the criteria for the delineation of sensitivity, specificity, positive and negative predictive values, and, when applicable, likelihood ratios.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Positional plagiocephaly

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Neurology

Pediatrics

Radiology

Intended Users

Physicians

Guideline Objective(s)

To answer the question "Is imaging necessary for infants with positional plagiocephaly to make a diagnosis?"

Target Population

Infants with positional plagiocephaly

Interventions and Practices Considered

1. Clinical examination
2. Skull x-rays
3. Ultrasound imaging of the suspect suture
4. Surface imaging (computer-based topographical scan)
5. Stereophotogrammetry
6. Computed tomography scan

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Utility of diagnostic imaging

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Search Strategy

Literature Search

The task force worked with medical librarians to determine appropriate search terms and to create search strategies for each guideline chapter. The National Library of Medicine and the Cochrane Library were searched for literature published between 1966 and October 2014. Task force members used the article inclusion/exclusion criteria described below to screen abstracts and provide a list of relevant articles for full-text review. Task force members were blinded to the selection of abstracts provided by other task force members. Congress of Neurological Surgeons (CNS) staff compiled lists of manuscripts for full-text review and approval by all of the task force members, and these full-text articles were reviewed by all task force members. In addition, task force members also screened the bibliographies of relevant systematic reviews for potentially relevant articles.

Article Inclusion Criteria

Included articles must have met certain criteria, as detailed below. To reduce bias, these criteria were specified before conducting the literature searches. To be included in the review, an article had to meet the following criteria:

- Studies had to investigate pediatric (<18 years of age) patients with non-synostotic plagiocephaly or brachycephaly.
- Studies with mixed patient populations and that combined the results of these patient groups must have enrolled ≥80% of pediatric patients with plagiocephaly or brachycephaly.
- The study was a full article report of a clinical study.
- Studies had to have appeared in a peer-reviewed publication or a registry report.
- Studies had to enroll at least 10 patients (5 per treatment arm) for each distinct outcome measured. If it was a comparative study, a minimum enrollment of 5 patients per treatment arm for each outcome was necessary.
- The study involved humans.
- The study was published in or after 1966.
- The study presented results quantitatively.
- The study did not involve "in vitro," "biomechanical," or results performed on cadavers.

- The study was published in English.

Systematic reviews, meta-analyses, or guidelines developed by others were not considered as evidence to support this guideline. The task force screened the bibliographies of these publications to ensure the accuracy and comprehensiveness of the literature search results used for this guideline.

Specific Search Strategy for This Guideline

Literature Search

The task force members collaborated with medical librarians to search the National Library of Medicine/PubMed database and the Cochrane Library for the period from 1966 to October 2014 using the MeSH subject headings and PubMed search strategies provided in Appendix A of the full version of the guideline (see the "Availability of Companion Documents" field). Manual searches of bibliographies were also conducted.

Search Results

The searches resulted in 204 abstracts. The task force selected 42 full-text articles for review. Of these, 10 were rejected for not meeting inclusion criteria or for being off-topic (see Figure 1 in the full version of the guideline [see the "Availability of Companion Documents" field]).

Number of Source Documents

Thirty-two articles were selected for systematic review. See Figure 1 in the full version of the guideline (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence and Levels of Recommendation on Diagnosis

Class I Evidence Level I (or A) Recommendation	Evidence provided by one or more well-designed clinical studies of a *diverse* population using a "gold standard" reference test in a blinded evaluation appropriate for the diagnostic applications and enabling the assessment of sensitivity, specificity, positive and negative predictive values, and, when applicable, likelihood ratios.
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Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Abstracts were reviewed and an evidentiary table was assembled summarizing the studies and the quality of evidence.

Rating Quality of Diagnostic Evidence

For diagnostic-type papers, evidence classification had definitions targeted toward diagnosis. The issues addressed by papers on diagnosis are related to the ability of the diagnostic test to successfully distinguish between patients who have and do not have a disease or pertinent finding. This speaks to the validity of the test and is illustrated in the "Rating Scheme for the Strength of the Evidence" field. Additional information regarding the hierarchy classification of evidence can be located on the Congress of Neurological Surgeons (CNS) Web site (see also the "Availability of Companion Documents" field).

Many of the imaging studies were not designed to address the diagnostic utility of the imaging modality, and authors were actually assessing the utility of the imaging in longitudinal follow-up, not initial diagnosis. For this reason, some of the studies reviewed were downgraded in Level of Evidence.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

The development of these guidelines was initiated by the Congress of Neurological Surgeons (CNS) and the Section on Pediatric Neurosurgery in response to members' concerns about the variation in the diagnosis and treatment paradigms being utilized. A multidisciplinary team comprised of physician volunteers (clinical experts), a clinical guidelines expert, and medical librarians was convened to conduct a systematic search of the literature and prepare clinical guidelines on the topic of pediatric plagiocephaly. After initial discussions, the members of the Plagiocephaly Guideline Task Force (hereinafter referred to as "the task force") decided, a priori, that the 4 major sub-topics would include: imaging modalities in the diagnosis of plagiocephaly, repositioning, physical therapy, and molding orthoses (helmet therapy).

Strength of Recommendations Rating Scheme

The task force used the methodologies endorsed by the Joint Guidelines Committee (JGC) to assign a strength of recommendation for each recommendation included in this guideline. Linking evidence to recommendations, through the utilization of evidentiary tables, has been endorsed by the American Medical Association (AMA), the CNS, and the American Association of Neurological Surgeons (AANS). This process validates and supports the relationship between the strength of evidence and the strength of recommendations.

Demonstrating the highest degree of clinical certainty, Class I evidence is used to support recommendations of the strongest type, defined as Level I recommendations. Level II recommendations reflect a moderate degree of clinical certainty and are supported by Class II evidence or strong consensus of Class III evidence. Level III recommendations denote clinical uncertainty supported by inconclusive or conflicting evidence or expert opinion.

Voting on the Recommendations

The task force used voting among its members to approve the final recommendations, language, and strength of recommendations. The voting was used to ensure that the language of each recommendation accurately reflected the evidence and the strength of the evidence. All the recommendations in this review were approved following the first round of voting, and no further discussion was needed to finalize the recommendations. The voting technique is referred to as the nominal group technique. During the course of editing and finalization of the document, changes were made to allow recommendations to conform to the rules of evidence and language as described above. When this occurred, the changes were reviewed and approved by the group.

Guideline Panel Consensus and Approval Process

Topic teams were created from the task force based on expertise of the task force members with respect to each topic addressed within the review. Each group took part in literature selection, review of the literature, creation of the evidence tables, creation of the guideline, editing, and final review. The final draft of the guideline was then circulated to the entire task force for feedback, discussion, and ultimately approval.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Following task force approval, drafts of the completed guidelines were presented to the Joint Guidelines Committee (JGC) for peer review and, ultimately, recommendation of endorsement by the Congress of Neurological Surgeons (CNS) and the American Association of Neurological Surgeons (AANS). The reviewers for the JGC were vetted by the editorial staff of the journal *Neurosurgery*. During the review process, the peer reviewers were blinded to the identities of the task force members. As part of the evaluation process, reviewers could provide input on the content and the methodologies used to create the systematic review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field). 2 Class II and 30 Class III studies were included.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The diagnosis of true craniosynostosis is important because this condition is amenable to surgical correction, whereas positional, posterior plagiocephaly without synostosis (PWS) is adequately treated with repositioning, physical therapy, or, in moderate to severe cases, a cranial molding helmet. It has been the experience of many craniofacial specialists, including those on the Plagiocephaly Task Force, that most infants with plagiocephaly can be adequately diagnosed through a detailed clinical examination. Three dimensional (3-D) topographical scanning may be useful for diagnosis and baseline assessment of severity. In those rare cases in which the clinical examination was equivocal, skull x-rays or an ultrasound of the suture in question could be used to rule out craniosynostosis. Only if those radiological studies are equivocal, should a computed tomography (CT) scan of the head be performed.

Potential Harms

- False-positive and false-negative results of imaging
- Risk of radiation exposure in infancy is of obvious concern, and unnecessary computed tomography (CT) scans should be avoided.

Qualifying Statements

Qualifying Statements

Disclaimer of Liability

This clinical systematic review and evidence-based guideline was developed by a physician volunteer task force as an educational tool that reflects the current state of knowledge at the time of completion. The presentations are designed to provide an accurate review of the subject matter

covered. This guideline is disseminated with the understanding that the recommendations by the authors and consultants who have collaborated in its development are not meant to replace the individualized care and treatment advice from a patient's physician(s). If medical advice or assistance is required, the services of a physician should be sought. The recommendations contained in this guideline may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in this guideline must be made by a managing physician in light of the situation in each particular patient and on the basis of existing resources.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mazzola C, Baird LC, Bauer DF, Beier A, Durham S, Klimo P Jr, Lin AY, McClung-Smith C, Mitchell L, Nikas D, Tamber MS, Tyagi R, Flannery AM. Congress of Neurological Surgeons systematic review and evidence-based guideline for the diagnosis of patients with positional plagiocephaly: the role of imaging. Neurosurgery. 2016 Nov;79(5):E625-6. [2 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Nov

Guideline Developer(s)

Congress of Neurological Surgeons - Professional Association

Source(s) of Funding

These evidence-based clinical practice guidelines were funded exclusively by the Congress of Neurological Surgeons and the Section on Pediatric Neurosurgery of the Congress of Neurological Surgeons and the American Association of Neurological Surgeons, which received no funding from outside commercial sources to support the development of this document.

Development of this systematic review and set of guidelines was editorially independent of the funding agencies.

Guideline Committee

Plagiocephaly Guideline Task Force

Composition of Group That Authored the Guideline

Task Force Members: Catherine Mazzola, MD, Goryeb Children's Hospital of Atlantic Health Systems, Morristown, New Jersey; Lissa C. Baird, MD, Department of Neurological Surgery, Oregon Health and Science University, Portland, Oregon; David F. Bauer, MD, Dartmouth–Hitchcock Medical Center, Lebanon, New Hampshire; Alexandra Beier, DO, Division of Pediatric Neurosurgery, University of Florida Health Jacksonville, Jacksonville, Florida; Susan Durham, MD, Division of Neurosurgery, University of Vermont Medical Center, Burlington, Vermont; Paul Klimo Jr, MD, Semmes-Murphey Neurologic & Spine Institute, Department of Neurosurgery, University of Tennessee Health Science Center, Le Bonheur Children's Hospital, Memphis, Tennessee; Alexander Y. Lin, MD, St. Louis Cleft-Craniofacial Center, SSM Health Cardinal Glennon Children's Hospital at Saint Louis University, Division of Plastic Surgery, Saint Louis University School of Medicine, St. Louis, Missouri; Catherine McClung-Smith, MD, Department of Neurological Surgery, Palmetto Health University of South Carolina Medical Group, Columbia, South Carolina; Laura Mitchell, MA, Guidelines Department, Congress of Neurological Surgeons, Schaumburg, Illinois; Dimitrios Nikas, MD, Department of Neurosurgery, University of Illinois at Chicago, Chicago, Illinois, Advocate Children's Hospital, Oak Lawn, Illinois; Mandeep S. Tamber, MD, PhD, Department of Pediatric Neurological Surgery, Children's Hospital of Pittsburgh of UPMC, Pittsburgh, Pennsylvania; Rachana Tyagi, MD, Department of Surgery, Division of Neurosurgery, Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey; Ann Marie Flannery, MD, Kids Specialty Center, Women's & Children's Hospital, Lafayette, Louisiana

Financial Disclosures/Conflicts of Interest

Potential Conflicts of Interest

All guideline task force members were required to disclose all potential conflicts of interest (COIs) prior to beginning work on the guideline, using the COI disclosure form of the Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) (hereinafter referred to as the Joint Guidelines Committee). The CNS Guidelines Committee and the task force chair reviewed any disclosures and either approved or disapproved the nomination and participation on the task force. The CNS Guidelines Committee and the task force chair may approve nominations of task force members with possible conflicts and restrict the writing, reviewing, and/or voting privileges of that person to topics that are unrelated to the possible COIs.

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

Guideline Endorser(s)

American Academy of Pediatrics - Medical Specialty Society

American Association of Neurological Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Neurosurgery Web site . Also available as ePub from the Neurosurgery Web site .

Availability of Companion Documents

The following are available:

- Congress of Neurological Surgeons systematic review and evidence-based guideline for the diagnosis of patients with positional plagiocephaly: the role of imaging. Full guideline. 2016 Nov. 42 p. Available from the Congress of Neurological Surgeons (CNS) Web site .
- Flannery AM, Mitchell L, Mazzola C, Klimo P Jr., Baird LC, Tamber MS, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Nikas D, Tyagi R. Congress of Neurological Surgeons systematic review and evidence-based guideline for the management of patients with positional plagiocephaly: introduction and methods. 2016 Nov. 12 p. Available from the CNS Web site .
- Flannery AM, Tamber MS, Mazzola C, Klimo P Jr, Baird LC, Tyagi R, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Mitchell L, Nikas, D. Congress of Neurological Surgeons systematic review and evidence-based guidelines for the management of patients with positional plagiocephaly: executive summary. Neurosurgery. 2016 Nov;79(5):623-4. Available from the Neurosurgery Web site .
- Congress of Neurological Surgeons (CNS). Guideline development methodology: endorsed by the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Guideline Committee. Schaumburg (IL): Congress of Neurological Surgeons (CNS); 2012 Feb. 12 p. Available from the CNS Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 3, 2017. The information was verified by the guideline developer on February 23, 2017.

Copyright Statement

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